NDA 16-798/S-048
NDA 17-516/S-018

Pfizer Inc.
Attention: Jeannette A. Barrett, Ph.D.
235 East 42nd Street
New York, NY 10017-5755

APR 10 2000

Dear Dr. Barrett:

Please refer to your supplemental new drug applications S-048 (NDA 16-798) and S-018 (NDA 17-516) dated August 23, 1999, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for SINEQUAN (doxepin HCl) capsules and Oral Concentrate.

Supplemental applications S-048 and S-018 provide the addition of new labeling text describing the safety and efficacy of doxepin HCI in the geriatric population in accordance with 21 CFR 201 .57(f)(1 0). The specific additions are as follows:

1. PRECAUTIONS- **Drowsiness** Subsection
"Sedating drugs may cause confusion and over sedation in the elderly; elderly patients generally should be started on low doses of SINEQUAN and observed closely (see PRECAUTIONS-Geriatric Use)."

2. PRECAUTIONS-**Geriatric Use** Subsection (New)
"**Geriatric Use**: A determination has not been made whether controlled clinical studies of SINEQUAN included sufficient numbers of subjects aged 65 and over to define a difference in response from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.[1,2] In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the labeling text provided under these supplements. Accordingly, the applications are approved.

The final printed labeling (FPL) must be identical to the draft labeling text submitted on August 23, 1999.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Should any questions arise concerning these NDAs, please contact Mr. Paul David, Regulatory Project Manager, at (301) 594-5530.

Sincerely yours,

Russell G. Katz, M.D.
Director
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